IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiff, v. ACTAVIS LLC; APOTEX, INC.; APOTEX, CORP.; BEDFORD LABORATORIES; DR. REDDY'S LABORATORIES, INC.; DR. REDDY'S LABORATORIES LTD.; EMCURE PHARMACEUTICALS USA, INC.; EMCURE PHARMACEUTICALS, LTD; HOSPIRA, INC.; PHARMACEUTICS INTERNATIONAL INC.; PHARMAFORCE, INC.; SAGENT PHARMACEUTICALS, INC.; ACS DOBFAR INFO S.A.; STRIDES, INC.; AGILA SPECIALTIES PRIVATE LTD.; SUN PHARMACEUTICALS INDUSTRIES, INC.; SUN PHARMA GLOBAL FZE; CARACO PHARMACEUTICAL LABORATORIES, LTD; SUN PHARMACEUTICAL INDUSTRIES LTD.; TEVA PARENTERAL MEDICINES, INC.; WOCKHARDT USA LLC; and WOCKHARDT LTD. Defendants.	Civil Action No. 13-1028 (SDW)

COMPLAINT

1. Plaintiff Novartis Pharmaceuticals Corporation ("Novartis") alleges as follows on personal knowledge as to its own actions and observations, and on information and belief as to all other facts.

NATURE OF THE ACTION

2. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. The defendants are seeking approval from the U.S. Food and Drug Administration ("FDA") to manufacture and sell generic versions of a drug called zoledronic acid. This drug was discovered by scientists at Novartis and thereafter was tested in extensive clinical trials. Ultimately, the FDA approved zoledronic acid to be sold by Novartis and it is now available as two different products: Zometa® for oncology uses and Reclast® for osteoporosis and Paget's disease.

3. On March 2, 2013 the exclusivity granted to Novartis by the FDA for zoledronic acid will expire. However, Novartis has been awarded three U.S. Patents that cover the methods of using zoledronic acid and its approved presentations. This action seeks to enjoin the defendants from launching their generic versions of zoledronic acid until Novartis' patent rights can be enforced.

4. The three patents awarded to Novartis by the U.S. Patent and Trademark Office are: U.S. Patent No. 8,324,189 ("the '189 patent") directed to oncology methods, U.S. Patent No. 8,052,987 ("the '987 patent") directed to methods for treating abnormally increased bone turnover, and U.S. Patent No. 7,932,241 ("the '241 patent") directed to certain approved presentations for zoledronic acid.

5. Upon information and belief, some or all of the defendants intend to launch their generic versions of zoledronic acid on or soon after March 2, 2013, but before the expiration of

Novartis' patent rights. Novartis seeks immediate relief to enjoin the defendants from launching their generic versions of zoledronic acid until Novartis can enforce its three patents.

THE PARTIES

A. Novartis

6. Plaintiff Novartis is a corporation organized under Delaware law. Its principal place of business is in East Hanover, New Jersey. Novartis owns the '241, '987, and '189 patents.

B. The Generic Defendants

a) Actavis LLC

7. Actavis LLC ("Actavis") is a limited liability company organized under Delaware law. Its principal place of business is in Morristown, New Jersey.

8. Upon information and belief, Actavis has submitted to the FDA an ANDA seeking approval to sell a generic version of Zometa.

b) Apotex, Inc. and Apotex Corp.

9. Apotex Corp. is a corporation organized under Delaware law. Its principal place of business is in Weston, Florida.

10. Apotex Inc. is a corporation organized and existing under the laws of Canada, having its principal place of business in Toronto, Canada. Upon information and belief, Apotex Inc. and Apotex Corp. (collectively "Apotex") are in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the United States, including in this judicial district.

11. Upon information and belief, Apotex have systematic and continuous contacts with New Jersey, including New Jersey distributors and significant sales in New Jersey. Apotex has also availed itself of the legal protections of the State of New Jersey by, among other things,

admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

12. Upon information and belief, Apotex Inc. has submitted to the FDA an ANDA seeking approval to market a generic version of Reclast.

13. Upon information and belief, Apotex Inc. has submitted to the FDA ANDA No. 78533, seeking approval to market a generic version of Zometa. Upon information and belief, Apotex has tentative approval from the FDA with regard to its ANDA No. 78533.

c) Bedford Laboratories

14. Bedford Laboratories is a trade name for Ben Venue Laboratories, Inc., a corporation organized under Delaware law. Its principal place of business is in Bedford, Ohio.

15. Bedford Laboratories develops, manufactures and sells generic versions of branded drugs in the United States, including in New Jersey. Upon information and belief, Bedford Laboratories has systematic and continuous contacts with New Jersey, including New Jersey distributors and significant sales in New Jersey.

16. Upon information and belief, Bedford Laboratories has submitted to the FDA ANDA No. 78768, seeking approval to market a generic version of Zometa. Upon information and belief, Bedford Laboratories has received tentative approval from the FDA with regard to its ANDA No. 78768.

d) Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.

17. Dr. Reddy's Laboratories, Inc. is a corporation organized under New Jersey law. Its principal place of business is in Bridgewater, New Jersey.

18. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a wholly-owned subsidiary of Dr. Reddy's Laboratories, Ltd., a corporation organized and existing under the laws

of India, having its principal place of business in Hyderabad, India. Dr. Reddy's Laboratories Ltd. has availed itself of the legal protections of the State of New Jersey by, among other things, creating a subsidiary with its principal place of business in New Jersey (*i.e.*, Dr. Reddy's Laboratories, Inc.).

19. Upon information and belief, Dr. Reddy's Laboratories, Ltd. and its U.S. subsidiary Dr. Reddy's Laboratories, Inc. (collectively "Dr. Reddy's Laboratories") are in the business of, among other things, developing, manufacturing, and/or selling generic versions of branded pharmaceutical products for distribution in the United States, including in this judicial district.

20. Upon information and belief, Dr. Reddy's Laboratories submitted to the FDA ANDA Nos. 91363 and 91364, seeking approval for a generic version of Reclast. Upon information and belief, Dr. Reddy's Laboratories has received tentative approval from the FDA for its ANDA Nos. 91363 and 91364.

21. Upon information and belief, Dr. Reddy's Laboratories submitted to the FDA two ANDAs seeking approval for generic versions of Zometa. Upon information and belief, Dr. Reddy's Laboratories has received tentative approval from the FDA for its ANDA No. 91186.

e) Emcure Pharmaceuticals USA, Inc. and Emcure Pharmaceuticals Ltd.

22. Emcure Pharmaceuticals USA, Inc. is a corporation organized under New Jersey law. Its principal place of business is in East Brunswick, New Jersey.

23. Upon information and belief, Emcure Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Emcure Pharmaceuticals, Ltd., a corporation organized and existing under the laws of India, having its principal place of business in Pune, India. Emcure Pharmaceuticals, Ltd. has availed itself of the legal protections of the State of New Jersey by, among other things, creating a

subsidiary with its principal place of business in New Jersey (*i.e.*, Emcure Pharmaceuticals USA, Inc.).

24. Upon information and belief, Emcure Pharmaceuticals, Ltd., and its U.S. subsidiary Emcure Pharmaceuticals, Inc. (collectively "Emcure") are in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the United States, including in this judicial district.

25. Upon information and belief, Emcure Pharmaceuticals, Ltd. submitted to the FDA ANDA No. 201801, seeking approval to market a generic version of Reclast. Upon information and belief, Emcure Pharmaceuticals, Ltd. has obtained tentative approval from the FDA with regard to ANDA No. 201801.

26. Upon information and belief, Emcure Pharmaceuticals, Ltd. submitted to the FDA two ANDAs seeking approval to market generic versions of Zometa. Upon information and belief, Emcure Pharmaceuticals, Ltd. has obtained tentative approval from the FDA with regard to ANDA No. 201783.

f) Hospira, Inc.

27. Hospira, Inc. ("Hospira") is a corporation organized under Delaware law. Its principal place of business is in Lake Forest, Illinois.

28. Upon information and belief, Hospira has systematic and continuous contacts with New Jersey, including offices in New Jersey, New Jersey distributors and significant sales in New Jersey. Upon information and belief, Hospira develops, manufactures and sells generic versions of branded drugs in the United States, including in New Jersey.

29. Upon information and belief, Hospira submitted to the FDA an ANDA seeking approval for a generic version of Reclast.

30. Upon information and belief, Hospira submitted to the FDA ANDA Nos. 90621 and 90709, seeking approval for a generic version of Zometa. Upon information and belief, Hospira has obtained tentative approval from the FDA with regard to ANDA No. 90621 and 90709.

g) Pharmaceutics International, Inc.

31. Pharmaceutics International, Inc. ("PII") is a corporation organized under Maryland law. Its principal place of business is in Hunt Valley, Maryland.

32. Upon information and belief, PII develops, manufactures and sells generic versions of branded drugs in the United States, including in New Jersey. Upon information and belief, PII has systematic and continuous contacts with New Jersey, including engagements to strategically develop, market, deliver, and/or sell generic products in New Jersey.

33. Upon information and belief, PII submitted to the FDA an ANDA seeking approval to market a generic version of Reclast.

34. Upon information and belief, PII submitted to the FDA ANDA No. 91170, seeking approval to market a generic version of Zometa. Upon information and belief, PII has obtained tentative approval from the FDA with regard to its ANDA No. 91170.

h) Pharmaforce, Inc.

35. Pharmaforce, Inc. ("Pharmaforce") is a corporation organized under Delaware law. Its principal place of business is in Columbus, Ohio.

36. Upon information and belief, Pharmaforce develops, manufactures and sells generic versions of branded drugs in the United States, including in New Jersey. Upon information and belief, Pharmaforce has systematic and continuous contacts with New Jersey, including New Jersey distributors.

37. Upon information and belief, Pharmaforce submitted to the FDA ANDA No. 90330,

seeking approval to market a generic version of Zometa. Upon information and belief, Pharmaforce has obtained tentative approval from the FDA with regard to its ANDA No. 90330.

i) Sagent Pharmaceuticals, Inc. and ACS Dobfar Info S.A.

38. Sagent Pharmaceuticals, Inc. is a corporation organized under Delaware law. Its principal place of business is in Schaumburg, Illinois. Upon information and belief, Sagent develops, manufactures and sells generic versions of branded drugs in the United States, including in New Jersey.

39. Sagent is the U.S. agent of ACS Dobfar Info S.A. ("ACS Dobfar"), a corporation organized under Swiss law. ACS Dobfar's principal place of business is in Campascio, Switzerland. Upon information and belief, ACS Dobfar alone or in concert with Sagent and/or its New Jersey distributors and suppliers, manufactures, distributes, imports and/or sells generic versions of branded drugs in the United States, including in New Jersey.

40. Upon information and belief, ACS Dobfar submitted to the FDA an ANDA seeking approval to market a generic version of Reclast.

41. Upon information and belief, ACS Dobfar submitted to the FDA New Drug Application ("NDA") No. 203231, seeking approval to market a generic version of Zometa. Upon information and belief, ACS Dobfar has obtained tentative approval from the FDA with regard to its NDA No. 203231.

j) Sun Pharmaceuticals Industries, Inc.; Sun Pharma Global FZE; Caraco Pharmaceutical Laboratories, Ltd.; and Sun Pharmaceutical Industries Ltd.

42. Sun Pharmaceuticals Industries, Inc. is a corporation organized under Michigan law. Its principal place of business is in Cranbury, New Jersey.

43. Sun Pharma Global FZE is a corporation organized under the laws of the United

Arab Emirates. Its principal place of business is in Sharjah, United Arab Emirates.

44. Caraco Pharmaceutical Laboratories, Ltd. is organized under Michigan law. Its principal place of business is in Detroit, Michigan.

45. Sun Pharmaceutical Industries, Ltd. is a corporation organized under Indian law. Its principal place of business is in Mumbai, India.

46. Sun Pharmaceuticals Industries, Inc., Sun Pharma Global FZE, and Caraco Pharmaceutical Laboratories, Ltd. are wholly-owned subsidiaries of Sun Pharmaceutical Industries, Ltd. (collectively "Sun"). Sun develops, makes, and sells generic drugs throughout the United States, including in New Jersey. Sun has availed itself of the legal protections of the State of New Jersey by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of New Jersey.

47. Upon information and belief, Sun submitted to the FDA an ANDA seeking approval to market a generic version of Reclast.

48. Upon information and belief, Sun submitted to the FDA three ANDAs seeking approval to market generic versions of Zometa. Upon information and belief, Sun has obtained tentative approval from the FDA with regard to its ANDA No. 90018.

k) Strides Inc. and Agila Specialties Private Ltd.

49. Strides, Inc. is a corporation organized under New Jersey law. Its principal place of business is Lambertville, New Jersey. Strides Inc. is a wholly owned subsidiary and agent of Strides Arcolab Ltd., an Indian company.

50. Agila Specialties Private Ltd. ("Agila") is a company organized under Indian law. Its principal place of business is in Bangalore, India. Upon information and belief, Agila is also a wholly owned subsidiary of Strides Arcolab Ltd. and is the specialties unit of Strides Arcolab Ltd.

51. Upon information and belief, Agila has submitted to the FDA an ANDA, seeking to sell a generic version of Reclast.

52. Upon information and belief, Strides is the U.S. agent for Agila (collectively "Strides"). Upon information and belief, defendants Agila and Strides Inc. are wholly owned subsidiaries of Strides Arcolab that act in concert with respect to collaborating in the development, manufacturing, marketing, and sale of generic copies of branded pharmaceutical products. On information and belief, Strides imports, distributes, manufactures, markets, and/or sells generic versions of branded drugs in the United States, including in New Jersey.

l) Teva Parenteral Medicines, Inc.

53. Teva Parenteral Medicines, Inc. is a corporation organized under Delaware law. Its principal place of business is in Irvine, California. Upon information and belief, Teva develops, makes, and sells generic drugs throughout the United States, including in New Jersey.

54. Upon information and belief, Teva submitted to the FDA an ANDA seeking approval to market a generic version of Reclast.

55. Upon information and belief, Teva submitted to the FDA ANDA Nos. 78576 and 78580, seeking approval to market generic versions of Zometa. Upon information and belief, Teva has obtained tentative approval from the FDA with regard to ANDA Nos. 78576 and 78580.

m) Wockhardt USA, LLC and Wockhardt Ltd.

56. Wockhardt USA, LLC is a limited liability company organized under Delaware law. Its principal place of business is in Parsippany, New Jersey. Upon information and belief, Wockhardt develops, makes, and sells generic drugs throughout the United States, including in New Jersey. Wockhardt USA, LLC is a wholly-owned subsidiary of Wockhardt Ltd. (collectively "Wockhardt").

57. Wockhardt Ltd. is a limited liability company organized under Indian law. Its principal place of business is in Mumbai, India. Wockhardt Ltd. has availed itself of the legal protections of the State of New Jersey by, among other things, creating a subsidiary with its principal place of business in New Jersey (*i.e.*, Wockhardt USA, Inc.).

58. Upon information and belief, Wockhardt Ltd. has submitted to the FDA an ANDA seeking approval to market a generic version of Reclast.

59. Upon information and belief, Wockhardt Ltd. has submitted to the FDA an ANDA seeking approval to market a generic version of Zometa.

JURISDICTION AND VENUE

60. This action seeks to enforce federal patent rights under federal law. Accordingly, this Court has federal question jurisdiction under 28 U.S.C. §§ 1331 and 1338(a) and declaratory judgment jurisdiction under 28 U.S.C. §§ 2201 and 2202.

61. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b).

62. This Court has personal jurisdiction over defendants for the following reasons, among others:

i. All defendants have sold generic drugs in New Jersey, and are seeking approval and/or have obtained tentative approval to sell and/or distribute generic versions of Reclast and/or Zometa in New Jersey;

ii. Novartis, which will be harmed by the defendants' actions, is domiciled in New Jersey;

iii. Defendants Actavis, LLC; Dr. Reddy's Laboratories, Inc.; Emcure Pharmaceuticals USA, Inc.; Strides, Inc.; Sun Pharmaceutical Industries, Inc.; and Wockhardt USA, LLC have their principal place of business in New Jersey;

iv. Defendants Actavis, Apotex, Bedford Laboratories, Dr. Reddy's Laboratories, Emcure Pharmaceuticals, Hospira, PII, Pharmaforce, Sagent, Sun, Strides, Teva, and Wockhardt have systematic and continuous contacts with New Jersey, in that, among other things, they sell, manufacture, import and/or distribute generic drugs in New Jersey;

v. Defendants Sun and Wockhardt are already before this Court in litigation involving one or more of the patents at issue here, C.A. No. 12-cv-04393-SDW-MCA and C.A. No. 2:12-cv-03967-SDW-MCA, respectively.

STATEMENT OF FACTS

A. Novartis' Branded Products

63. The active ingredient in Zometa is zoledronic acid. Zometa was first approved by the FDA in 2001 and is used to treat hypercalcemia of malignancy (HCM), a condition resulting in high calcium blood levels due to cancer, multiple myeloma and bone metastases from solid tumors. Zometa's primary indication is for the prevention of skeletal-related complications associated with cancer, such as fractures and pain.

64. Zometa is administered intravenously as a 4 mg dose of zoledronic acid diluted in standard buffer media. Zometa has been sold in three forms: (a) a "pre-concentrate" vial of 4 mg of Zometa diluted in 5 mg of buffer, which must be further diluted before administration to a patient; (b) a "Ready to Use" or "RTU" vial of 4 mg of Zometa in fully diluted form; and (c) a 4 mg vial of powder, which would be diluted by an infusion center before administration to a patient (this product was discontinued in 2003).

65. The active ingredient of Reclast is also zoledronic acid. Reclast was first approved by the FDA in 2007 and is used to treat osteoporosis, a condition in which bones become weakened, and Paget's disease, a clinically rare genetic condition that disrupts the normal cycle of

bone cell turnover.

66. Reclast is also administered intravenously, although the dosage of zoledronic acid in Reclast is different than Zometa. Reclast is administered as a 5 mg dose diluted in standard buffer media. Reclast is sold only in a liquid form that is fully diluted and ready to be administered.

B. The Patents-In-Suit

67. The '241 patent, entitled "Pharmaceutical products comprising bisphosphonates," was duly and legally issued on April 26, 2011 and is owned by Novartis. The '241 patent's inventors discovered that zoledronic acid could not be stored for extended periods in then-industry-standard glass vials. The acid tends to degrade the glass, resulting in particles that can contaminate the drug. Accordingly, Novartis scientists invented a novel plastic-coated vial able to hold zoledronic acid for extended periods. The '241 patent is directed to this invention. A copy of the '241 patent is attached as Exhibit A.

68. The '987 patent, entitled "Method of administering bisphosphonates," was duly and legally issued on November 8, 2011 and is owned by Novartis. After extensive clinical experimentation, Novartis scientists discovered that Reclast could be effective when administered once per year, once every two years, or even less frequently. The '987 patent is directed to these methods of treatment. A copy of the '987 patent is attached as Exhibit B.

69. The '189 patent, entitled "Use of zolendronate for the manufacture of a medicament for the treatment of bone metabolism diseases," was duly and legally issued on December 4, 2012, and is owned by Novartis. During clinical trials of Zometa, Novartis scientists learned that cancer patients could suffer renal toxicity—*i.e.*, kidney damage—if the drug were administered too quickly. After extensive clinical experimentation, however, Novartis scientists discovered that renal toxicity could be controlled if Zometa were administered as a 4 mg dose over a 15 minute period. The '189 patent is directed to this method of treatment. A copy of the '189 patent is

attached as Exhibit C.

70. Zometa and Reclast and their methods of use are covered by one or more claims of the '241, '987, and '189 patents, which have been listed in connection with Zometa and Reclast in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations, which is also referred to as the "Orange Book." Accordingly, the defendants have actual or constructive knowledge of each of the patents.

C. The ANDA Process

71. The FDA regulates the manufacture, sale and labeling of prescription drugs in the U.S. Under the 1984 Hatch-Waxman Act, companies wishing to bring a generic version of a branded prescription drug to market can submit an Abbreviated New Drug Application (ANDA) to the FDA. 21 U.S.C. § 355(j). This ANDA process allows the generic drug maker to avoid the expensive clinical trials required of an NDA holder to demonstrate a drug's safety and effectiveness. The generic company simply relies on the original NDA submission for that purpose.

72. The Hatch-Waxman Act also contains provisions meant to balance the interests of branded and generic companies in resolving claims concerning the branded company's patents. The Act requires drug makers to identify the patents covering their drugs in the Orange Book. 21 U.S.C. § 355(b)(1)(c)(2). When seeking ANDA approval, the applicant must take certain actions with respect to listed patents. Applicants have two options pertinent here.

73. First, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), an applicant can assert that the branded drug's patent(s) is/are invalid, unenforceable, and/or will not be infringed, a so-called "Paragraph IV certification." Such a certification is provided to the FDA and notice is given to the NDA holder and patent owner. Upon receiving notice of the certification, the NDA holder or patent owner can choose to enforce its patents in federal court.

74. Second, under 21 U.S.C. § 355(j)(2)(A)(viii), an applicant can attempt to seek a label only for uses not covered by a branded drug's method-of-use patent(s), a so-called "Section viii carve-out." If the generic drug is ultimately approved, the FDA will require the generic drug maker to duplicate only that portion of the branded drug's label not protected by the applicable method-of-use patents, as identified in the Section viii carve-out.

D. The Generics' ANDA Applications

75. As noted above, defendants and/or their non-U.S. parent company or affiliates have submitted ANDAs seeking approval to manufacture and sell generic versions of one or more forms of Zometa, and/or to sell a generic version of Reclast.

76. With regard to the '241 patent, defendants Hospira, PII, and Sagent have notified Novartis that they have submitted ANDAs to the FDA seeking approval to market generic versions of Reclast prior to expiration of the '241 patent. Upon information and belief, defendant Sagent also submitted to the FDA an NDA seeking approval to market a generic version of Zometa prior to expiration of the '241 patent. These defendants' (Hospira's, PII's, and Sagent's) Paragraph IV notices with regard to the '241 patent have asserted that the patent is invalid and/or not infringed. Additionally, upon information and belief, defendant Teva must include a Paragraph IV certification with regard to the '241 patent in its ANDA prior to obtaining final approval. Thus, while Novartis has not yet received a Paragraph IV notice from Teva, it anticipates receiving such notices shortly and, in any event, prior to the marketing of Teva's ANDA product.

77. With regard to the '189 patent, five defendants (Actavis, Dr. Reddy's Laboratories, PII, Sun, and Wockhardt) have notified Novartis that they have submitted ANDAs to the FDA seeking approval to market generic versions of Zometa prior to expiration of the '189 patent. Upon information and belief, defendant Sagent notified Novartis it has submitted to the FDA an NDA seeking approval to market a generic version of Zometa prior to expiration of the '189

patent. These defendants (Actavis, Dr. Reddy's Laboratories, PII, Sagent, Sun, and Wockhardt) have provided Paragraph IV notices asserting that the patent is invalid and/or not infringed. Upon information and belief, seven defendants (Apotex, Bedford Laboratories, Emcure, Hospira, Pharmaforce, Sun, and Teva) must include a Paragraph IV certification with regard to the '189 patent in their ANDAs prior to obtaining tentative or final approval for their ANDAs. Thus, while Novartis has not yet received Paragraph IV notices from these seven defendants, it anticipates receiving such notices shortly and, in any event, prior to those defendants marketing their ANDA products.

78. With regard to the '987 patent, defendants seeking approval for generic Reclast appear to be adopting two theories. First, Hospira and Wockhardt have served Paragraph IV notices contending that the Reclast patent is invalid.

79. The Reclast NDA is only approved for the following uses: (1) osteoporosis, *i.e.*, treatment and prevention of postmenopausal osteoporosis, treatment to increase bone mass in men with osteoporosis, and treatment and prevention of glucocorticoid-induced osteoporosis, and (2) treatment of Paget's disease of bone in men and women. Upon information and belief: there are eight defendants seeking approval to market generic versions of Reclast who have not served Paragraph IV notices as to the '987 patent (Apotex, Dr. Reddy's Laboratories, Emcure, PII, Sagent, Strides, Sun, and Teva); those defendants have filed with the FDA Section viii carve-out letters, stating that they will not use the osteoporosis indication in their labeling; and those defendants contend that the '987 patent does not cover Paget's disease.

80. Upon information and belief, these defendants' representations that their proposed ANDA products will not be offered for sale or sold for the treatment of osteoporosis is knowingly incorrect. Ninety-nine and seven-tenths percent (99.7%) of patients who take Reclast each year

are being treated for osteoporosis, *not* Paget's disease. Only three-tenths percent (0.3%) of patients who take Reclast do so for Paget's disease. Upon information and belief, approximately 350,000 patients are currently in treatment with Reclast. Of these 350,000 patients, only about 1,000 patients have Paget's disease.

81. Despite the relatively small size of the market for treatment of Paget's patients, no fewer than ten separate generic companies have submitted ANDAs for permission to sell Reclast. According to the U.S. Department of Health and Human Services, however, it typically costs generic drug makers $1 million to $2 million to bring a generic drug to market. Assuming these averages hold here, the generic Reclast defendants have each likely spent substantially more than the total size of the Paget's patient market in order to bring generic Reclast to market.

82. Doctors are free to, and frequently do, prescribe drugs for indications not identified in the drug's label. If the defendants market generic Reclast with a label limited to Paget's disease, doctors can nonetheless prescribe Reclast for cancer patients or for patients suffering from osteoporosis, a so-called "off-label use."

83. Accordingly, upon information and belief, the generic Reclast defendants intend to manufacture, offer for sale and sell generic Reclast in quantities that far exceed the market for treatment of Paget's disease. Upon information and belief, these defendants do not intend that their products be used only for treatment of Paget's disease, but in fact intend for there to be substantial use of their generic Reclast products for treatment of osteoporosis.

COUNT I (INFRINGEMENT OF THE '241 PATENT)

(Against defendants Hospira, PII, Sagent, and Teva)

84. Each of the preceding paragraphs 1 to 83 is incorporated as if fully set forth herein.

85. Defendants Hospira, PII, and Sagent have submitted ANDAs with Paragraph IV notices—and upon information and belief, Teva will file an amended ANDA with a Paragraph IV

notice imminently—to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of zoledronic acid solutions in a plastic-coated vial suitable to hold zoledronic acid as the active ingredient prior to the expiration of the approved presentations patent, which constitutes an act of infringement of one or more of the claims of the '241 patent under 35 U.S.C. § 271(e)(2)(A).

86. Upon FDA approval of their ANDAs (or NDA) and unless enjoined by the Court, Hospira, PII, Sagent, and Teva will further infringe the patent relating to approved presentations by making, using, offering to sell, and selling its zoledronic acid solutions in plastic-coated vial suitable to hold zoledronic acid as the active ingredient in the United States and/or importing such solutions into the United States in violation of 35 U.S.C. § 271(a).

87. There is an actual and justiciable case or controversy between Novartis and defendants Hospira, PII, Sagent, and Teva concerning the validity and infringement of the '241 patent. Novartis is entitled to a declaration that defendants Hospira's, PII's, Sagent's, and Teva's manufacture, use, sale, offer for sale, and/or importation of its generic Zometa and/or Reclast drug product in a plastic-coated vial suitable to hold zoledronic acid as the active ingredient will infringe one or more claims of the '241 patent and that the claims of the '241 patent are valid and enforceable.

COUNT II (INFRINGEMENT OF THE '987 PATENT)

(Against defendants Apotex, Dr. Reddy's Laboratories, Emcure, Hospira, PII, Sagent, Strides, Sun, Teva, and Wockhardt)

88. Each of the preceding paragraphs 1 to 87 is incorporated as if fully set forth herein.

89. Apotex's, Dr. Reddy's Laboratories', Emcure's, Hospira's, PII's, Sagent's, Strides', Sun's, Teva's, and Wockhardt's submissions of ANDAs to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Reclast for the same use claimed in the '987 patent constitutes an act of infringement of one or more of the claims of the Reclast patent

under 35 U.S.C. § 271(e)(2)(A). Upon final FDA approval of their ANDAs, and unless enjoined by the Court, Apotex, Dr. Reddy's Laboratories, Emcure, Hospira, PII, Sagent, Strides, Sun, Teva, and Wockhardt will indirectly infringe the '987 patent by making, using, offering to sell, and selling its zoledronic acid solutions containing the equivalent of 5 mg/ 100 mL of zoledronic acid as the active ingredient (Reclast) in the United States and/or importing such solutions into the United States.

90. Specifically, defendants will knowingly and intentionally induce patients to infringe the '987 patent in violation of 35 U.S.C. § 271(b).

91. Defendants will also contribute to infringement of the '987 patent by others, by knowingly offering to sell, selling, or distributing within the United States or importing into the United States generic Reclast, which has no substantial non-infringing uses, in violation of 35 U.S.C. § 271(c).

92. There is an actual and justiciable case or controversy between Novartis and defendants Apotex, Dr. Reddy's Laboratories, Emcure, Hospira, PII, Sagent, Strides, Sun, Teva and Wockhardt concerning the validity and infringement of the '987 patent. Novartis is entitled to a declaration that defendants Apotex's, Dr. Reddy's Laboratories', Emcure's, Hospira's, PII's, Sagent's, Strides', Sun's, Teva's, and Wockhardt's manufacture, use, sale, offer for sale, and/or importation of its generic Reclast drug product will infringe, contribute to the infringement of and/or actively induce the infringement of one or more claims of the '987 patent and that the claims of the '987 patent are valid and enforceable.

COUNT III (INFRINGEMENT OF THE '189 PATENT)

(Against Defendants Actavis, Apotex, Bedford Laboratories, Dr. Reddy's Laboratories, Emcure, Hospira, PII, Pharmaforce, Sagent, Sun, Teva and Wockhardt)

93. Each of the preceding paragraphs 1 to 92 is incorporated as if fully set forth herein.

94. Defendants Actavis, Dr. Reddy's Laboratories, Emcure, PII, Sun (for one formulation), and Wockhardt have submitted ANDAs with Paragraph IV notices, defendant Sagent submitted an NDA with a Paragraph IV notice, and upon information and belief, Apotex, Bedford Laboratories, Hospira, Pharmaforce, Sun (for at least one other formulation), and Teva will file amended ANDAs with Paragraph IV notices imminently, to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of generic Zometa for the same use claimed in the Zometa patent, which constitutes an act of infringement of one or more of the claims of the '189 patent under 35 U.S.C. § 271(e)(2)(A).

95. Upon FDA approval of the defendants' ANDAs (or NDA), and unless enjoined by the Court, Actavis, Apotex, Bedford Laboratories, Dr. Reddy's Laboratories, Emcure, Hospira, PII, Pharmaforce, Sagent, Sun, and Teva will indirectly infringe the Zometa patent by making, using, offering to sell, and selling its zoledronic acid solutions containing 4 mg zoledronic acid as the active ingredient in the United States and/or importing such solutions into the United States.

96. Specifically, defendants will knowingly and intentionally induce patients to infringe the '189 patent in violation of 35 U.S.C. § 271(b).

97. Defendants will also contribute to infringement of the '189 patent by others, by knowingly offering to sell, selling, or distributing within the United States or importing into the United States generic Zometa, which has no substantial non-infringing uses, in violation of 35 U.S.C. § 271(c).

98. There is an actual and justiciable case or controversy between Novartis and

defendants Actavis, Apotex, Bedford Laboratories, Dr. Reddy's Laboratories, Emcure, Hospira, PII, Pharmaforce, Sagent, Sun, Teva, and Wockhardt concerning the validity and infringement of the '189 patent. Novartis is entitled to a declaration that defendants Actavis's, Apotex's, Bedford Laboratories's, Dr. Reddy's Laboratories', Emcure's, Hospira's, PII's, Pharmaforce's, Sagent's, Sun's, Teva's and Wockhardt's manufacture, use, sale, offer for sale, and/or importation of its generic Zometa drug products will contribute to the infringement of and/or actively induce the infringement of one or more claims of the '189 patent and that the claims of the '189 patent are valid.

PRAYER FOR RELIEF

WHEREFORE, Novartis requests entry of judgment in its favor and against defendants as follows:

1. Declaring that the '241, '987, and '189 patents are valid and enforceable;

2. Declaring that the defendants have infringed, directly or indirectly, one or more claims of the '241, '987, and '189 patents;

3. An order preliminarily and permanently enjoining, pursuant to 35 U.S.C. § 283, and Fed. R. Civ. P. 65, and/or 35 U.S.C. § 271(e)(4)(A), the defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or in concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States generic versions of Reclast or Zometa until after the latest expiration date of the patent relating to approved presentations, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. Damages or other monetary relief to Novartis if defendants engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of generic versions of Reclast or Zometa prior to the latest expiration date of the '241, '987, and/or '189 patents,

including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

DATED: February 20, 2013

s/ William J. O'Shaughnessy
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

I certify that to the best of my knowledge, the matter in controversy is the subject of:

- *Novartis Pharmaceuticals Corporation et al. v. Wockhardt USA LLC et al.*, Civil Action No. 2:12-cv-03967-SDW-MCA filed on June 27, 2012 in the District of New Jersey; and

- *Novartis Pharmaceuticals Corporation et al. v. Sun Pharmaceuticals Industries Inc. et al.*, Civil Action No. 12-cv-04393-SDW-MCA filed on July 13, 2012 in the District of New Jersey.

Dated: February 20, 2013

Respectfully Submitted,

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